REMARKS

Amendments

Claims 6, 8-10, 23, 29-32 and 35-39 are under consideration in the instant Office Action. Claims 6, 8-9, 23, 30-32 and 37 have been amended. Claim 10 has been canceled. The amendments to the claims do not constitute new matter and are completely supported throughout the specification and originally filed claims. More particularly, support for the amendments can be found, for example, at page 8, lines 27-30, page 17, lines 4-16 and at page 56, line 13 through page 57, line 9, of the specification.

The foregoing amendments are made solely to expedite prosecution of the application and are not intended to limit the scope of the invention. Further, the amendments to the claims are made without prejudice to the pending or now canceled claims or to any subject matter pursued in a related application. The Applicant reserves the right to prosecute any canceled subject matter at a later time or in a later filed divisional, continuation, or continuation-in-part application.

Upon entry of the amendment, claims 6, 8-9, 23, 29-32, and 35-39 are pending in the instant application.

Rejections

Rejection under 35 U.S.C. § 101

The Examiner has rejected claims 6, 8-10, 23, 29-32 and 35-39 under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a specific or substantial asserted utility or a well-established utility. Applicant respectfully traverses the rejection. However, Applicant believes the rejection has been overcome in light of the claim amendments and arguments below.

Claims 6, 8-10, 23, 29-32 and 35-39 are directed to a transgenic mouse having a disruption in a FPR-RS4, wherein the mouse exhibits increased anxiety, decreased coordination or decreased susceptibility to seizure, relative to a wild-type mouse, to a method of producing the transgenic mouse, a cell or tissue obtained from the transgenic mouse, and to methods of using the mouse to screen for agents that may modulate or ameliorate a phenotype exhibited by the transgenic mouse.

The Examiner has alleged that Applicant has not provided a specific or substantial use for the transgenic mouse exhibiting the claimed phenotypes, and that there does not exist in the art such a use. The Examiner has based this conclusion on an alleged lack of correlation between the phenotypes exhibited by the claimed mouse and any specific disease or disorder. More particularly, the Examiner has asserted that there is not a correlation between increased anxiety, decreased coordination, decreased susceptibility to seizure or ataxia and any disease or disorder. Applicant asserts that such a correlation does exist, which is generally accepted within the art of transgenic and knockout mice.

As an example, Applicant asserts that a correlation does exist between a phenotype of increased anxiety as exhibited by the claimed mouse and the disorder of anxiety. More particularly, Applicant has established that disruption of the target gene, FPR-RS4, results in a transgenic mouse that exhibits anxious behavior when compared to a wild-type control mouse without the disruption. Applicant asserts that the skilled artisan would recognize that a direct correlation exists between the FPR-RS4 disruption and the increased anxiety, and thus would recognize a variety of uses for the transgenic mouse with the disruption for many anxiety related studies. Applicant submits that the above example applies also to the phenotypes of impaired coordination and abnormal seizure susceptibility exhibited by the claimed mice. A phenotype of impaired coordination resulting from disruption of FPR-RS4 relates to motor function and coordination problems, and seizure disorders are clearly a disease or disorder.

It is generally viewed in the art that when genes are knocked out or disrupted in mice, as in the present invention, the resulting phenotype reveals or is representative of the function of that gene. In the present case, the phenotypes of the transgenic mice comprising disrupted FPR-RS4 genes, specifically increased anxiety, decreased coordination or decreased susceptibility to seizure, indicates a role for FPR-RS4 in these conditions, and establishes the utility of the mice as models for such conditions or disorders, and for discovering treatments for such conditions or disorders. This is supported by the homology between the mouse and human genomes, and the general acceptance that gene function in the mouse is related to and representative of that of humans.

Despite Applicant's belief that a connection between the FPR-RS4 gene disruption and the phenotypes of the claimed transgenic mouse exists and/or is well-established in the art and the instant disclosure, Applicant is not aware of any requirement for expressly stating that a

correlation exists in order to satisfy the utility requirements set forth in 35 U.S.C. § 101, nor is it believed that the establishment of such a correlation is required for patentability of the transgenic mouse as claimed. Applicant submits that in order to satisfy these requirements, the specification must assert a specific and substantial utility that is credible to a skilled artisan, or the utility of the claimed invention must be apparent to the skilled artisan. See MPEP § 2107.

Applicant believes that he has asserted several uses for the transgenic mice claimed that would be credible to the skilled artisan. These include but are not limited to use as models for disease (*e.g.* a model of anxiety, impaired coordination or resistance to seizure), for identifying agents that ameliorate disease symptoms, for identifying agents that affect or modulate a phenotype caused by the gene disruption, or for determining the specificity of an agent targeting the FPR-RS4 gene (see, for example, page 17, lines 23-24, page 18, lines 8-19 and lines 24-28, and page 19, lines 7-11, of the specification). Applicant submits that these utilities of the claimed mouse would be immediately apparent to the skilled artisan, even absent Applicant's disclosure. The utility of transgenic knockout animals is well recognized in the art. However, even in the absence of a correlation between the phenotype(s) of the claimed mouse and a disease or disorder, a link between FPR-RS4 disruption and the claimed phenotypes of increased anxiety, impaired coordination and decreased seizure susceptibility in a mouse is clearly established. The skilled artisan would easily recognize the utility or value of the transgenic mouse for studying or investigating conditions related to FPR-RS4 in a mouse or related mammal. In this case, the skilled artisan could use the claimed mice to study the increased anxiety, impaired coordination or seizure susceptibility in mice, and to discover or develop treatments for such conditions in mice or related animals. Each of these are clearly "real world" uses for the claimed transgenic mice.

In light of the arguments set forth above, Applicant does not believe that the Examiner has properly established that the claimed invention lacks a specific and substantial utility. Applicant believes the rejection of the claims under 35 U.S.C. § 101 has been overcome in view of the amendments to the claims and arguments set forth above, and respectfully requests withdrawal of the rejection.

Rejection under 35 U.S.C. § 112, first paragraph

Enablement:

The Examiner has also rejected claims 6, 8-10, 23, 29-32 and 35-39 under 35 U.S.C. § 112, first paragraph, because one skilled in the art would allegedly not know how to use the transgenic mice as a result of the alleged lack of either a specific or substantial asserted utility or a well-established utility set forth in the above utility rejection. Applicants respectfully traverse the rejection. However, in view of the amendments to the claims and arguments in response to the utility rejection set forth above, Applicants submit that the rejection under 35 U.S.C. § 112, first paragraph, has been overcome.

In addition, the Examiner has rejected claims 6, 8-10, 23, 29-32 and 35-39 for various issues of enablement. Applicant traverses the rejection. However, Applicant submits that each aspect of the rejection has been overcome by the amendments to the claims as noted below.

The first aspect of the rejection relates to the unpredictability of a phenotype of a chimeric animal. More particularly, the Examiner has asserted that the breadth of the claims allegedly encompass chimeric animals wherein only a portion of the cells of the animal comprises the claimed genetic disruption. Applicant traverses this aspect of the rejection. However, Applicant submits that this aspect of the rejection is overcome in light of the amendments to the claims to recite a transgenic animal whose genome comprises the claimed disruption.

The Examiner has further rejected claim 10 as lacking enablement because it is not taught what assay one of skill in the art would perform to determine the effect of an agent of a gene or gene product not present in the animal. Applicant traverses the rejection. However, the rejection has been overcome by cancellation of claim 10.

The Examiner's rejection of claim 30 relates to its dependence on claim 6, which does not recite ataxia as a phenotype in light of the step in claim 30 which recites ameliorating ataxia. The Examiner states that it is not known how to determine whether an agent ameliorates ataxia in a mouse that does not exhibit ataxia. Applicant has overcome this rejection by amending the claim to delete the term ataxia in the determining step.

Written Description:

The Examiner has also rejected claim 37 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicant traverses the rejection.

Specifically, the Examiner states that the specification does not support the amendments made to the claim in the previous response. More particularly, the Examiner asserts that the limitation of a phenotype of decreased coordination **wherein the decreased coordination is characterized by falling off the accelerating rotarod at a lower speed**, is not supported. The Examiner has stated that the specification has only provided support for a decreased time to fall during the rotarod test. As the speed of rotation increases over time, a mouse that falls in decreased time would also fall at a decreased speed of rotation, and thus would fall off the accelerating rotarod at a lower speed. This is adequately described in the instant specification. See page 56, lines 15-17 and 20-21, and Figure 4, which support Applicant's statements. Applicants disagree that the claimed mouse is not supported by the specification. However, the amendments made to the claims overcome this aspect of the rejection in that the claims now recite that the decreased coordination is characterized by a decrease in the time to fall from the accelerating rotarod.

Applicant believes that the written description rejection has been overcome, and respectfully requests withdrawal of the rejection.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 6, 8, 9, 10, 29-32 and 35-39 were rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses the rejection.

Regarding claims 6, 9, 10 and 23, the Examiner states that the claims are indefinite in that the term "FPR-RS4" can be interpreted as the FPR-RS4 gene or the FPR-RS4 protein, and a protein cannot have a homozygous disruption. Applicant has overcome this aspect of the rejection by adopting the Examiner's suggestion to change "FPR-RS4" to "the FPR-RS4 gene".

In addition, claim 9 is asserted to be indefinite because the language of the preamble is directed to a genetic mosaic, while step (d) encompasses breeding the chimeric mouse to generate transgenic mice whose genome comprises a homozygous disruption in the FPR-RS4 gene. Applicant has overcome the rejection by amending the preamble to recite "a transgenic mouse whose genome comprises a homozygous disruption..."

With regard to claims 31 and 32, the Examiner asserts that it is unclear what "*in vivo* effects" are encompassed by the claims. Applicant's amendment of claims 31 and 32 overcome this aspect in that they no longer recite the phrase "*in vivo* effects."

In light of the amendments to the claims, each of the Examiner's rejections under 35 U.S.C. § 112, second paragraph, have been overcome. Applicant respectfully requests withdrawal of the rejection.

It is believed that the claims are currently in condition for allowance, and notice to that effect is respectfully requested. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1271 under Order No. R-632.

Respectfully submitted,

Date: March 10, 2004

Kelly L. Quast, Reg. No. 52,141

Deltagen, Inc.
1031 Bing Street
San Carlos, CA 94070
(650) 569-5100